

**REMARKS**

Claims 39-42 and 44-62 are pending in this application. Claims 39-42, 44-51, and 58-61 have been further amended and claims 52-57 and 62 have been cancelled. Upon entry of this amendment claims 39-42, 44-56, and 58-61 will be pending. Applicant has further amended the pending claims to better recite the present invention and overcome claim objections.

**Claim Rejections Under 35 U.S.C. § 112**

Claims 58 and 61-62 were rejected as failing to comply with the written description requirement, in particular based on the recitation of the term “monolith”. Applicants have amended these claims and cancelled claim 61 to remove such a recitation. Accordingly, Applicants respectfully contend that this rejection is traversed.

**Claim Objections**

Claims 42, 46-57, and 61-62 were rejected as positively a human body part. Applicants have amended claims 39, 42, and 46 to remove such a positive recitation and have cancelled claims 52-57. Accordingly, Applicants respectfully contend that this rejection is traversed.

**Prior Art Claim Rejections**

The Examiner has rejected claims 39, 41-42, 46-48, and 52-54 under 35 USC 102(e) as being anticipated by US Publication No. 20040236327 to Paul et al. The Examiner has rejected claims 39, 42, 46, 51-52, 57, and 59-60 under 35 USC 102(e) as being anticipated by US Publication No. 20040143264 to McAfee. The Examiner has rejected claims 44-45, 49-51, and 55-62 under 35 USC 103(a) as being obvious over the US Publication No. 20040236327 to Paul et al.

The Examiner has rejected claim 40 under 35 USC 103(a) as being obvious over the US Publication No. 20040143264 to McAfee in view of US Patent No. 6,530,934 to Jacobsen et al.

Claim 39 as amended:

A connection system for use in a bone fixation device, comprising:  
a first bone coupling assembly adapted to be secured to a first vertebrae;  
a rod comprising:  
    a rigid first end portion including a surface received at least partially by and coupled to the first bone coupling assembly;  
    a rigid second end portion;  
    a longitudinal *flexible, substantially inelastic* member located between the first end portion and the second end portion, *fixably* coupled to the first end portion, and *fixably* coupled to the second end portion; and  
    a *rigid* spacer located between the first and second ends portions and circumferentially disposed about the longitudinal flexible, substantially inelastic member;  
a second bone coupling assembly coupled to the rod at a location other than the first end portion and adapted to be secured to a second vertebrae, the second vertebra adjacent to the first vertebrae,  
    wherein the first and second ends portions *directly* limit motion of the rigid spacer along the longitudinal flexible, substantially inelastic member and the rigid spacer limits the minimum distance between the first vertebrae and the second vertebrae when the rod is coupled to the first vertebrae and the second, adjacent vertebrae via the first bone coupling assembly and the second bone coupling assembly.

The Paul reference in figures 12 and 12a disclosures an “encased spring concept” having rods 102 attached to an elastic middle element 110 via attachment means 108 and a cross sectional diagram of a tube 106 having a flange 104. The Paul reference clearly discloses an elastic member (coupled to the rods), in particular a spring 110. As amended claim 39 recites a flexible, *substantially inelastic* member. The Paul reference at paragraph 0092 states “[t]he tube 106 preferably has a diameter sufficient to allow movement of the rods 102 and attachment means 108 in response to the movement of the spring”. Clearly, the Paul reference only discloses encasing the spring 110 and ends 102 with a tube 106 that has an inner diameter greater than the outer diameter of the rods 102. Accordingly, the rods 102 do not and cannot *directly limit* the motion of the spacer

(tube 106 in Paul) as recited in claim 39 (as amended). Accordingly, Applicants respectfully contend that claim 39 is not obvious or anticipated by the Paul reference.

The McAfee reference in Figures 5 and 11 describes a system including several metal pedicle attachment sleeves that slide on a rod where there may be a polymer bumper between two metal attachment sleeves. McAfee discloses in paragraph 0005 that the invention is a “novel vertebral anchor spinal rod sleeve system that allows a vertebra to slide cephalad or caudad along a spinal rod system”. McAfee does not disclose a connection system that includes a *flexible* member; McAfee only discloses a metal rod. Further McAfee does not disclose a *flexible* member *fixably* coupled to a first end portion where the first end portion is coupled to a first bone coupling assembly. The metal attachment sleeves of McAfee are slidably coupled to the McAfee rod. Further, the McAfee reference does not disclose a rigid spacer; the McAfee reference only discloses a polymer bumper. Additionally, McAfee also does not limit the distance between two vertebra given the metal sleeves are slidably coupled to a non-flexible rod. Accordingly, Applicants respectfully contend that claim 39 is not obvious or anticipated by the McAfee reference.

#### Claim 40

Claim 40 is dependent on claim 39. Accordingly, Applicants respectfully contend that claim 40 is not anticipated or obvious in view the McAfee reference and the Paul reference. Claim 40 further recites that the rigid spacer includes an interlocking female or male member that interlocks with a rigid end portion or another spacer. The Examiner had presented US Patent 6,530,934 to Jacobsen as a reference that discloses spacers having a male or a female interlocking element, in particular Fig. 6 and Fig. 8. Applicants respectfully contend that the invention recited by Jacobsen reference is in an unrelated art area – cardiovascular technology and designed to accomplish a difference purpose. Accordingly, Applicants contend that it would not be obvious to combine the Jacobsen reference to disclosure the additional limitations of claim 40.

Claims 41, 42, 44, 45 and 58-60

Claims 41, 42, 44, 45 and 58-60 are directly or indirectly dependent on claim 39. Accordingly, Applicants respectfully contend that claims 41, 42, 44, 45 and 58-60 are not anticipated or obvious in view the McAfee reference and the Paul reference.

Claim 46 as amended:

A connection system, comprising:  
a rod comprising:  
    a rigid first element;  
    a rigid second element;  
    a ***flexible, substantially inelastic*** longitudinal element located between the first element and the second element and ***fixably*** coupled to one of the first element and the second element; and  
    a ***rigid*** third element located between the first and second elements and circumferentially disposed about the longitudinal element;  
a first bone coupling assembly connected to the rod, the first bone coupling assembly adapted to secure the rod to a first vertebrae of a patient;  
a second bone coupling assembly connected to the rod at a different location than the first bone coupling assembly, the second bone coupling assembly adapted to secure the rod to a second vertebrae, the second vertebra adjacent to the first vertebrae of the patient;  
wherein the third element limits the minimum distance between the first vertebrae and the second, adjacent vertebrae when the rod is coupled to the first vertebrae and the second vertebrae via the first bone coupling assembly and the second bone coupling assembly.

Similar to claim 39, claim 46 as amended recites a flexible, *substantially inelastic* member. The Paul reference clearly discloses an elastic member (coupled to the rods), in particular a spring 110. Accordingly, Applicants respectfully contend that claim 46 is not obvious or anticipated by the Paul reference.

McAfee does not disclose a connection system that includes a *flexible* member; McAfee only discloses a metal rod. Further McAfee does not disclose a *flexible* member *fixably* coupled to one of a first end portion and a second end portion where an end portion is coupled to a bone

coupling assembly. The metal attachment sleeves of McAfee are slidably coupled to the McAfee rod. Further, the McAfee reference does not disclose a rigid spacer; the McAfee reference only discloses a polymer bumper. McAfee also does not limit the distance between two vertebra given the metal sleeves are slidably coupled to a non-flexible rod. Accordingly, Applicants respectfully contend that claim 46 is not obvious or anticipated by the McAfee reference.

Claims 47, 49, 50, and 61

Claims 47, 49, 50, and 61 are directly or indirectly dependent on claim 46. Accordingly, Applicants respectfully contend that claims 47, 49, 50, and 61 are not anticipated or obvious in view the McAfee reference and the Paul reference.

Claim 48

Claim 48 is dependent on claim 46. Accordingly, Applicants respectfully contend that claim 48 is not anticipated or obvious in view the McAfee reference and the Paul reference. Claim 48 further recites that first and second elements each have an outer diameter that is greater than an inner diameter of the third element. The Paul reference only discloses encasing the spring 110 and ends 102 with a tube 106 that has an inner diameter greater than the outer diameter of the rods 102. Accordingly, Applicants contend that claim 48 is not anticipated or obvious in view the McAfee reference and the Paul reference.


**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Please contact the undersigned Attorney to discuss any remaining issues or claim proposals.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-1119** referencing docket no. **559552000123**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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